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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,643	10/14/2005	Philippe Chalvignac	SAIME 3.3-003	1454
530	7590	07/06/2009	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			STUART, COLIN W	
ART UNIT	PAPER NUMBER			
		3771		
MAIL DATE	DELIVERY MODE			
07/06/2009	PAPER			

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,643	<b>Applicant(s)</b> CHALVIGNAC, PHILIPPE
	<b>Examiner</b> COLIN STUART	<b>Art Unit</b> 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 21 April 2006.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-24 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-24 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 14 October 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s)/Mail Date <u>10/14/05</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____

#### **DETAILED ACTION**

1. This action is in response to the preliminary amendment filed 4/21/06. No new claims have been added nor any claims been cancelled. Currently, claims 1-24 are pending in the instant application.

#### ***Specification***

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The term "consisting of" in line 1 is improper language.

#### ***Information Disclosure Statement***

3. The information disclosure statement filed 10/14/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Note: the documents not considered have been crossed through.

***Drawings***

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "100a" and "100b" have both been used to designate a turbine. Similarly, other elements have been given different reference numerals in figures depicting different embodiments, and require correction as well.

The drawings are objected to because Figs. 3-9 are missing units for the axes of the graphs. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The language "disabling means" lacks enablement because one of ordinary skill in the art would be unable to make the device as claimed without any further disclosure clarifying the disabling means.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 4, 9, 14, and 21, the use of the language "elaborating" or "elaborates" is unclear because the examiner cannot properly ascertain the claimed limitation based on the ordinary definition in the art.

Regarding claims 1, 6-11, and 22, the use of the language "associated to" is unclear because the examiner cannot ascertain if the following recited structure or limitations are positively being claimed.

Regarding claims 6-8, 12, 18-20, and 24, it is unclear what structure present in the invention is performing the memorization of the various speed values. The examiner therefore cannot ascertain how these speed values are being used in the claimed comparison steps.

Claims 8 and 20 recites the limitation "the end of an expiratory cycle" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the start of a new expiratory cycle" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 16 recites the limitation "the turbine rotor" in line 3. There is insufficient antecedent basis for this limitation in the claim.

#### ***Claim Rejections - 35 USC § 101***

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The language "to carry the pressurised gas to a patient" in claim 1 line 5 appears to be claiming the human body in the functional language. The examiner suggests amending to read --adapted to carry the pressurised gas to a patient--.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1, 3-7, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Brydon (5,740,795).**

In regards to claims 1 and 3, Brydon shows a breathing assistance device which includes a turbine 14 to generate a flow of pressurized respiratory gas, a duct ("air delivery tube (not shown)" col. 3 ln. 31) to carry the pressurized gas to a patient, and control means 18 for controlling gas pressure capable of elaborating a pressure setting for the turbine. Brydon's device also inherently has a speed sensor capable of acquiring a signal corresponding to a rotation speed of a rotating element of the turbine ("motor speed and power measurements" col. 3 ln. 8). Turbines inherently have a rotating element which is directly related to the speed of the turbine. Brydon's device further includes means of calculation (col. 3 ln. 10-23) connected to the speed sensor to elaborate the pressure setting of the turbine using the signal from the speed sensor ("speed feedback signal 22 is input to the motor controller 18 to provide a signal upon which speed regulation can be based" col. 3 ln. 37-39).

In regards to claim 4, Brydon's device includes calculation means which use the speed signals to elaborate a pressure setting according to variations in speed ("these measured signals vary" col. 3 ln. 10).

In regards to claim 5, Brydon's device includes means of calculation which use speed signals "to detect the points at which the patient starts to inhale or exhale" (col. 3 ln. 15-16) and adapts the level of pressure setting (col. 3 ln. 37-39).

In regards to claims 6, 7, and 11, Brydon's device also includes a "microcomputer where the subsequent signal processing described above is performed" (col. 4 ln. 38). This microcomputer employs signal processing programs to detect "the start of inhalation and exhalation" (col. 3 ln. 67 - col. 4 ln. 1). The programs uses "previously determined pressure/flow/speed characteristics of the turbine system" along with the actual instantaneous speed signal 22 and "threshold value for detecting inhalation and exhalation" (col. 4 ln. 25-26). Brydon's reference discloses an "instantaneous power signal" (col. 3 ln. 60) which is employed in the signal processing and is directly related to the instantaneous speed of the turbine. The speed signal is the speed bearing as in claim 7 because direction of the flow can be ascertained in that a positive value would indicate flow going into the patient.

In regards to claim 13, Brydon's device uses a microcomputer, which is a microprocessor, to perform signal processing and comparison of the speed signals to detect inhalation/exhalation cycles.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. **Claims 8-9, 15-21, and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brydon (5,740,795).**

In regards to claim 8, Brydon's reference has everything as claimed including speed sensor and a computer (calculation means). Brydon lacks a detailed description of using a program to detect an inspiratory cycle using a comparison between a memorized speed value representative of a speed at the end of an expiratory cycle and an actually measured instantaneous speed. However, the feature of comparing the predetermined speed to the real time speed is well known in the art for obtaining desired speed. In addition, using a program to calculate or determine the desired speed is common practice and is necessary for carrying out the calculations. Furthermore, Brydon's reference is capable of obtaining a speed at the end of expiratory cycles. Thus, the feature of having a program to compare the memorized speed value at the end of the expiratory cycle and the actual measured speed fails to patentably define over the prior art.

In regards to claims 9 and 21, the Brydon's reference employs a microcomputer to perform signal processing and comparison as discussed above but is silent as to using several programs for comparison. However, one of ordinary skill in the art at the time of the invention would have found it obvious to use various programs

simultaneously for comparison to increase the accuracy of the inhalation/exhalation detecting process.

In regards to claims 15-20 and 23-24, Brydon lacks a detailed description of the claimed method steps. However, Brydon's system has the same structure as claimed. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made upon seeing Brydon's system, that the system would be able to perform the claimed method steps.

**12. Claims 10, 12, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brydon (5,740,795) as applied to claim 6, 11, or 18 above, and further in view of Rapoport et al. (5,803,066).**

In regards to claims 10 and 22, the Brydon's reference teaches all the limitations as discussed above, but, as best understood, is silent as to providing a disabling means to compensate for the momentary pause between inspiratory and expiratory cycles. However, Rapoport teaches a breathing assistance device and control method which includes a pause state which allows the "machine is in transition from INSP to EXP, or from EXP to INSP" (Rapoport col. 7 ln. 56-57) for a determined duration following the start of the cycle. Therefore, one of ordinary skill in the art at the time the invention was made would have found it obvious to modify the Brydon's device and method to include a disabling means, or pause state, as taught by Rapoport in order to provide a more accurate control method for the breathing assistance device.

In regards to claim 12, the Brydon's reference teaches all the limitations as discussed above, but is silent as to the memorized turbine speed values being maximum values for an inspiratory cycle. However, Rapoport teaches a breathing assistance device and control method in which the "system determines the maximum inspiratory flow value" (Rapoport col. 8 ln. 39-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brydon's device and method to also use memorized maximum turbine speed values for an inspiratory, as taught by Rapoport, in its comparison method in order to provide a more accurate control method as the modified method would be taking measurements from points through out the respiration cycles as opposed to focusing on the transitions from inspiratory to expiratory cycles.

**13. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brydon (5,740,795) as applied to claims 1 or 18 above, and further in view of Farrugia et al. (6,332,463).**

In regards to claim 2, the Brydon's reference teaches all the limitations as discussed above, but is silent as to the speed sensor being a Hall effect sensor. However one of ordinary skill in the art at the time of the invention would have found this to be a matter of obvious design choice as a Hall effect sensor is well-known in the art and further taught by Farrugia's breathing assistance control method (Abstract line 3).

In regards to claim 14, Brydon's reference teaches all the limitations as discussed above including a circuit which connects the speed sensor, calculation

means, and turbine for elaborating the speed setting input for the turbine (Brydon col. 4 ln. 36-48, but is silent as to the pressure-regulating "feedback loop" (Brydon col. 2 ln. 58) further including a pressure sensor on the duct. However, Farrugia teaches a breathing assistance device and control method which includes a pressure sensor (42 Farrugia) which is connected to breathing tube, or duct, (40 Farrugia). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Brydon's reference to include a pressure sensor as taught by Farrugia in order to provide a more direct, and accurate, measurement of the pressure of the breathing gas delivered to a patient.

### ***Conclusion***

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Jafari et al. (6,626,175), Champain et al. (5,443,061), and Servidio et al. (5,927,274) are all related to ventilation regulation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771